

polymerizable material; said core polymeric material having an oxygen permeability equal to or greater than 69 barrers; wherein said surfaces are hydrophilically modified by a treatment process selected from the group consisting of coating processes, grafting processes, plasma treating processes, electrical charge treating processes and irradiation processes; and wherein said extended wear contact lens can be continuously worn for at least four days on a human eye without substantial corneal swelling and without having substantial amounts of lipid adsorption.

188. (Amended). The extended contact lens of claim 187 wherein said core polymeric material formed from N-vinyl pyrrolidone.

192. (Amended). A siloxane hydrogel contact lens having modified surfaces, said hydrogel contact lens comprising a core polymeric material having an oxygen permeability equal to or greater than 69 barrers, said hydrogel contact lens being suited to make contact with ocular tissue and ocular fluids and having a high oxygen permeability and a high ion permeability, said core polymeric material being formed from polymerizable materials comprising:

- (a) an oxyperm polymerizable material, and
- (b) an ionoperm polymerizable material,

wherein said lens has a high oxygen permeability and allows ion or water permeation in an amount sufficient to enable the lens to move on the eye such that corneal health is not substantially harmed and wearer comfort is acceptable during a period of continuous contact with ocular tissue and ocular fluids, wherein said lens has an oxygen permeability of at least about 69 barrers and an ion permeability characterized either by an Ionoflux Ion Diffusion Coefficient of greater than about  $6.4 \times 10^{-6}$  mm<sup>2</sup>/sec or an Ionoton Ion Permeability Coefficient of greater than about  $0.4 \times 10^{-6}$  cm<sup>2</sup>/min,

wherein said modified surfaces are hydrophilically modified surfaces that are modified by a treatment process selected from the group consisting of coating processes, grafting processes, plasma treating processes, electrical charge treating processes and irradiation processes,

wherein said hydrogel contact lens is adapted for at least 24 hours of continuous wear on a human eye without substantial corneal swelling and without having substantial amounts of lipid adsorption.

193. (Amended). The hydrogel contact lens of claim 192 wherein said core polymeric material is formed from N-vinyl pyrrolidone as said ionoperm material.

205. (Amended). The method of claim 199, wherein said lens produces, after wear of about 24 hours, including normal sleep periods, less than about 8% corneal swelling.

207. (Amended). A method of forming a biocompatible lens having high oxygen permeability and high water permeability, said method comprising the steps of:

- (a) forming a pre-polymer core formulation comprising an oxyperm polymerizable material, and an ionoperm polymerizable material, said oxyperm polymerizable material comprises between about 30% to about 70%, based on the total weight, of said reactive components formulation;
- (b) polymerizing the core in an atmosphere substantially free from oxygen;
- (c) altering the surface of said core material to produce a surface which is more hydrophilic than said core material; and
- (d) sterilizing the lens;

whereby said lens allows oxygen permeation in an amount sufficient to maintain corneal health and wearer comfort during a period of extended, continuous contact with ocular tissue and ocular fluids, and

whereby said lens allows ion permeation in an amount sufficient to enable the lens to move on the eye such that corneal health is not substantially harmed and wearer comfort is acceptable during a period of extended, continuous contact with ocular tissue and ocular fluids,

wherein said lens having adequate movement on the eye with blinking to promote adequate tear exchange and without producing significant corneal swelling, without

having substantial amounts of lipid adsorption, and without causing substantial wearer discomfort during the period of contact for at least 24 hours,

wherein said ophthalmic lens has an oxygen transmissibility of at least about 70 barrers/mm and an ion permeability characterized either by (1) an Ionoton Ion Permeability Coefficient of greater than about  $0.2 \times 10^{-6} \text{ cm}^2/\text{sec}$  or (2) by an Ionoflux Ion Permeability Coefficient of greater than about  $1.5 \times 10^{-6} \text{ mm}^2/\text{min}$ , wherein said ion permeability is measured with respect to sodium ions.

217. (Amended). The lens of claim 212, including © said lens being sterilized.

218. (Amended). A method for producing an extended wear contact lens, said contact lens comprising a core polymeric material which has a high oxygen permeability and a high ion or water permeability, which method comprises the steps of:

- a) preparing a lens formulation comprising an oxyprom polymerizable material, and an ionoprom polymerizable material, wherein said oxyprom polymerizable material comprises between about 30% to about 70%, based on the total weight, of reactive components of said lens formulation;
- b) placing said lens formulation in a lens mold;
- c) polymerizing said lens formulation in said mold to form a lens core material having inner and outer surfaces such that said oxyprom polymerizable material and said ionoprom polymerizable material of said lens formulation form separate oxyprom and ionoprom phases; said lens core material having an oxygen permeability equal to or greater than 69 barrers;
- d) removing said lens core material from said lens mold;
- e) subjecting said lens core material to a treatment to modify said surfaces of said lens core material, wherein the surface treatment makes said surfaces more hydrophilic or lipophobic and more biocompatible with the ocular tissue than said core material alone; and
- f) hydrating the treated lens core material to produce a hydrated extended wear contact lens,

wherein the modified surfaces of said lens in conjunction with the high oxygen and ion permeabilities of said core polymeric material allows said hydrated lens to be worn as extended wear lens that is worn for a continuous period of at least 24 hours without having substantial amounts of lipid adsorption.

219. (Amended). A method for producing an extended wear contact lens, said contact lens comprising a core polymeric material which has a high oxygen permeability and a high ion or water permeability, which method comprises the steps of:

- a) preparing a lens formulation comprising an oxypolymerizable material selected from the group consisting of siloxane-containing macromers, fluorine-containing macromers, siloxane-containing monomers and fluorine-containing monomers, and an ionopolymerizable material, wherein said oxypolymerizable material comprises between about 30% to about 70%, based on the total weight, of reactive components of said lens formulation;
- b) placing said lens formulation in a lens mold;
- c) polymerizing said lens formulation in said mold to form a lens core material having inner and outer surfaces such that said oxypolymerizable material and said ionopolymerizable material of said lens formulation form separate oxypolymer and ionopolymer phases; said lens core material having at least one continuous pathway from said inner surface to said outer surface for oxygen transmission therethrough;
- d) removing said lens core material from said lens mold;
- e) subjecting said lens core material to a treatment to modify said surfaces of said lens core material, wherein the surface treatment makes said surfaces more hydrophilic or lipophobic and more biocompatible with the ocular tissue than said core material alone; and
- f) hydrating the treated lens core material to produce a hydrated extended wear contact lens;

wherein the modified surfaces of said lens in conjunction with the high oxygen and ion permeabilities of said core polymeric material allows said hydrated lens to be

worn as extended wear lens that is worn for a continuous period of at least 24 hours with corneal swelling of less than about 8%.

223. (Amended). An extended wear contact lens comprising a core polymeric material and upper and lower surfaces, said core polymeric material comprising a silicone copolymer which provides a high ion permeability and a high oxygen permeability; wherein said silicone copolymer comprises an oxyperm polymerizable material selected from the group consisting of siloxane-containing macromers, siloxane-containing monomers, fluorine-containing macromers, siloxane containing monomers and fluorine-containing monomers, and an ionoperm polymerizable material selected from the group consisting of acrylates, methacrylates, polyalkylene glycols and N-vinyl pyrrolidones, wherein said core polymeric material has at least one continuous pathway from said upper surface to said lower surface for oxygen treatment; wherein said surfaces are hydrophilically modified by a treatment process selected from the group consisting of coating processes, grafting processes, plasma treating processes, electrical charge treating processes and irradiation processes; and wherein said extended wear contact lens can be continuously worn for at least four days on a human eye without substantial corneal swelling.

224. (Amended). The extended contact lens of claim 223 wherein said core polymeric material is formed from a mixture comprising a siloxane-containing macromer or a siloxane monomer, and N-vinyl pyrrolidone.

228. (Amended). A hydrogel contact lens having modified surfaces, said hydrogel contact lens comprising a core polymeric material having at least one continuous pathway between said surfaces for oxygen transmission therethrough, said hydrogel contact lens being suited to make contact with ocular tissue and ocular fluids and having a high oxygen permeability and a high ion permeability, said core polymeric material [having] formed from polymerizable materials comprising:

(a) an oxyperm polymerizable material selected from the group consisting of siloxane-containing macromers, siloxane-containing monomers, fluorine-containing macromers and fluorine-containing monomers, and

(b) an ionoperm polymerizable material selected from the group consisting of acrylates, methacrylates, polyalkylene glycols and N-vinyl pyrrolidones,

Wherein said lens has a high oxygen permeability and allows ion or water permeation in an amount sufficient to enable the lens to move on the eye such that corneal health is not substantially harmed and wearer comfort is acceptable during a period of continuous contact with ocular tissue and ocular fluids, wherein said lens has an oxygen permeability of at least about 70 barrers and an ion permeability characterized either by an Ionoflux Ion Diffusion Coefficient of greater than about  $6.4 \times 10^{-6}$  mm<sup>2</sup>/sec or an Ionoton Ion Permeability Coefficient of greater than about  $0.4 \times 10^{-6}$  cm<sup>2</sup>/min,

wherein said modified surfaces are hydrophilically modified surfaces that are modified by a treatment process selected from the group consisting of coating processes, grafting processes, plasma treating processes, electrical charge treating processes and irradiation processes,

wherein said hydrogel contact lens is adapted for at least 24 hours of continuous wear on a human eye without substantial corneal swelling.

234. (Amended). The hydrogel contact lens of claim 230 wherein said lens has an oxygen permeability of at least 75 barrers.

#### Remarks:

#### **I. One of Ordinary Skill In the Art Would Not be Motivated to Combine The Secondary References With The Primary References.**

As discussed at the interview, Applicants again traverse the Office Action for the following reasons, as it would not be obvious to one combine the above primary references with any of the secondary references. To the contrary, there is no motivation to one of skill in the art to combine the references. As stated in the preceding response, obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there **is some teaching, suggestion, or motivation to do** so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See, In re Fine, 837 F.2d 1071, 5